

**Notice of Allowability**

Application No.

10/043,787

Examiner

Iqbal Chowdhury, Ph.D.

Applicant(s)

YUAN, CHONG-SHENG

Art Unit

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/30/2006.
2. ☒ The allowed claim(s) is/are 1,4,6-9,13,18,19,23,24,28-31 and 52-56.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____  |

### **EXAMINER'S AMENDMENT**

A Terminal Disclaimer is received on 6/8/2006 and entered.

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment, which places this application in condition for allowance. During a telephone conversation conducted on 6/15/2006, the applicants requested an extension of time for 1 more MONTH(S) (total 2 months) and authorized the Director to charge Deposit Account No. 03-1952 the required fee of  $\$450.00 - 120.00 = \$330.00$  for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jie Zhou on June 13, 2006.

### **EXAMINER'S AMENDMENT**

In specification amendment of 6/14/2004, delete "now pending" in line 6 and insert "now abandoned" after December 6, 1999 in line 6.

Art Unit: 1652

In claim 1, part a), insert “a ” after “comprising” and delete “the” before “nucleotide”, and change “sequences” to “sequence” in line 3.

In claim 1, part a), insert “corresponding to” after “SAH hydrolase” in line 13.

In claim 1, part a), delete “is at” after “SAH hydrolase” in line 13.

In claim 1, part a), insert “SEQ ID NO: 1” after “432 in” in line 16.

In claim 1, part a), delete “said SAH hydrolase” after “432 in” in line 16 and 17.

In claim 1, part a), delete “38” after “consisting of” and delete “100” after “83” in line 14.

In claim 1, part a), delete “329” after “322” in line 15.

In claim 1, part a), delete “420” after “409” in line 15.

In claim 18, delete “a labeled SAH derivative” before “ or a labeled SAH analogue” and “SAH derivative,” before “or SAH analogue” in line 2-4.

In claim 19, delete “SAH derivative” before “or SAH analogue” in line 2.

In claim 28, delete “SAH derivative” before “or SAH analogue in line 2.

In claim 29, delete “SAH derivative” before “or SAH analogue in line 2.

In claim 53, delete “a labeled SAH derivative” before “ or a labeled SAH analogue” and “SAH derivative” before “or SAH analogue” in line 2-4.

In claim 54, delete “SAH derivative” before “or SAH analogue” in line 2.

Claims 36-50 are cancelled.

*Reasons for Allowance*

Art Unit: 1652

The following is an examiner's statement of reasons for allowance: The applicant has claimed a method for assaying homocysteine (Hcy), S-adenosylhomocysteine (SAH) or adenosine in a sample, which method comprises:

a) contacting a sample containing or suspected of containing Hcy, SAH or adenosine with a mutant SAH hydrolase derived from a SAH hydrolase, wherein said SAH hydrolase is encoded by a nucleic acid comprising the nucleotide sequences selected from the group consisting of SEQ ID NO: 185, SEQ ID NO: 186, SEQ ID NO: 187, and SEQ ID NO: 188;

wherein said mutant SAH hydrolase has binding affinity for Hcy, SAH or adenosine but has attenuated catalytic activity, and wherein said binding affinity and/or said attenuated catalytic activity of said mutant SAH hydrolase is caused by a mutation in said mutant SAH hydrolase catalytic site, its binding site for NAD<sup>+</sup>, NADH. Hcy, SAH, adenosine, or a combination thereof; and wherein the mutant SAH hydrolase; i) has a mutation in an amino acid residue that participates in catalysis or that is directly interacting with NAD<sup>+</sup>, NADH. Hcy, SAH, adenosine; or ii) has a mutation in an amino acid residue that is adjacent to an amino acid residue that participates in catalysis that is directly interacting with NAD<sup>+</sup>, NADH. Hcy, SAH, adenosine, wherein the mutation in said mutant SAH hydrolase corresponding to one or more amino acid positions selected from the group consisting of 53, 54, 57, 59, 80, 83, 121, 131, 134, 155, 157, 158, 159, 181, 190, 191, 214, 221, 226, 235, 240, 248, 263, 269, 285, 292, 301, 309, 372, 347, 351, 353, 361, 362, 379, 386, 388, 398, 401, 407, 409, 424, 425, 426, 427, 428, 429, 430, 431, and 432 in SEQ ID NO: 1; and

b) detecting binding between Hcy, SAH or adenosine with said mutant SAH hydrolase, whereby the presence or amount of Hcy, SAH or adenosine in said sample is assessed.

Art Unit: 1652

The prior art does not teach or suggest a method for assaying homocysteine (Hcy), S-adenosylhomocysteine (SAH) or adenosine in a sample, which method comprises: contacting a sample containing or suspected of containing Hcy, SAH or adenosine with a mutant SAH hydrolase derived from a SAH hydrolase, wherein the mutation in said mutant SAH hydrolase is at one or more amino acid positions corresponding to a protein in SEQ ID NO: 1. The closest prior art is Yuan et al. (J. Biol. Chem. 271 (45): 28009-28016, 1996, see IDS). Yuan et al. teach a human placental SAH hydrolase which comprises the amino acid sequence as set forth in SEQ ID NO: 1 and having modification of three of the 10 cysteine residues per enzyme subunit resulted in complete inactivation of the enzyme. Yuan et al. do not teach any mutants as recited above nor teach the assay methods.

A standard search did not produce any prior art that suggests or teaches the claimed invention. The claimed invention is novel and nonobvious over the prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, PhD, Patent Examiner  
Art Unit 1652 (Recombinant Enzymes)  
US Patent and Trademark Office  
Rm. REM 2B69, Mail Box. 2C70  
Ph. (571)-272-8137, Fax. (571)-273-8137

IC

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1800  
16A